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JUN 30 2011

Exactech® Octane®-C Interbody Fusion System
Traditional 510(k)

510(k) Summary

Company:	Exactech®, Inc 2320 Northwest 66th Court Gainesville, FL 32653-1630
Date:	January 26, 2011
Contact Person:	Patrick Hughes Regulatory Affairs Specialist Phone: 352-327 4762 Fax: 352-378-2617 E-mail: patrick.hughes@exac.com
Proprietary Name:	Exactech® Octane®-C Interbody Fusion System
Common Name:	Intervertebral body fusion system

Classification Name:
Intervertebral Fusion Device - Cervical (21 CFR 888.3080, Class II, Product Code ODP)

Legally Marketed Devices to Which Substantial Equivalence Is Claimed
Phantom™ Plus Cage System (#K082801)
BAK Cervical Interbody Fusion Device (#P980048)

Device Description
This submission proposes a new Cervical Interbody Fusion System. The Octane®-C Interbody Fusion System is designed to provide stability during intervertebral body fusion in the cervical spine. Implantable Octane-C devices incorporate a 6° lordotic configuration, are manufactured from PEEK-Optima with 6% barium sulphate, titanium pins, and tantalum beads added for radiographic visibility; are provided sterile, and are designed to be implanted using a direct anterior approach and autogenous bone graft material.

Indications for Use
The Octane-C Interbody Cervical devices are intended for anterior cervical spine intervertebral body fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone.

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine (i.e., anterior plate systems).

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Patients must have undergone a regimen of at least six (6) weeks non-operative treatment prior to being treated with this device.

Summary of Technological Characteristics
The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use**
  The proposed Octane-C Interbody Fusion System devices and cited predicates are intended to be used with autogenous bone graft and an anterior surgical approach for treatment of degenerative disc disease at the levels of C3-C7.
- **Materials**
  Octane-C Interbody Fusion System devices and cited predicate devices are made from the same materials, with demonstrable histories of safe and effective use in medical applications, per internationally recognized consensus standards.
- **Dimensions**
  Octane-C Interbody Fusion System devices and cited predicate devices have substantially equivalent dimensions and will be available in substantially equivalent size ranges as cited predicate devices.
- **Sterilization processes**
  Octane-C Interbody Fusion System devices and cited predicate devices are provided sterile, and are sterilized using equivalent sterilization processes conforming to recognized industry standards.
- **Performance specifications**
  Mechanical testing results summarized in this 510(k) premarket notification demonstrate Octane-C Interbody Fusion System devices have substantially equivalent performance characteristics compared to legally marketed predicates based on testing per ASTM F2077, ASTM F2267, and clinically relevant biomechanical loads:
  - Static Compression
  - Static Torsion
  - Static Compressive Shear
  - Dynamic Compression
  - Dynamic Torsion
  - Dynamic Compressive Shear
  - Subsidence
  - Expulsion

Substantial Equivalence Conclusion
The Octane-C Interbody Fusion System is substantially equivalent to cited predicates per intended use, materials, dimensions, sterilization processes, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 30 2011

Exactech®, Inc.
% Mr. Patrick Hughes
Regulatory Affairs Specialist
2320 Northwest 66th Court
Gainesville, Florida 32653-1630

Re: K103655
Trade/Device Name: Exactech® Octane®-C Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: June 22, 2011
Received: June 23, 2011

Dear Mr. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Octane®-C Interbody Fusion System
Traditional 510(k)

Indications for Use Statement

510(k) Number: K103655

Device Name: Exactech® Octane®-C Interbody Fusion System

INDICATIONS FOR USE:
The Octane-C Interbody Cervical devices are intended for anterior cervical spine intervertebral body fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone.

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine (i.e., anterior plate systems).

Patients must have undergone a regimen of at least six (6) weeks non-operative treatment prior to being treated with this device.

Prescription Use __X__ and/or **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103655